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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/965,751

09/28/2001

Allan S. Myerson

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7590

11/12/2003

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,751

Applicant(s)

MYERSON ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 11-23, 25-42, 44, 46-50 and 52-59 is/are rejected.
- 7) ☒ Claim(s) 8, 10, 24, 43, 45 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2001 and 09 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

There is no copendency between the instant application and application no. 09/348,200, which became abandoned on November 8, 2000.

The status of the applications referred to in the priority claim should be updated.

Correction is required.

The benefit claims filed on June 9, 2003 and on September 23, 2003 were not entered because the required reference was not timely filed within the time period set forth in 37 CFR 1.78(a)(2) or (a)(5). If the application is an application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a nonprovisional application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the reference to the prior application must be made during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, applicant must file a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) or (a)(6). The petition must be accompanied by: (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted); (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay

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between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Note that the requirement to petition applies when the relationship between parent applications is incorrectly stated, as well as when a priority claim is completely missing from an application. See the Notice by Deputy Commissioner Kunin dated February 24, 2003, at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/benefitclaims.pdf>.

2. Applicant is advised that should claim 46 be found allowable, claim 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 3 and 46 are identical in scope.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-5, 11-21, 25-39, 46-49, and 52-59 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-88 of copending Application No. 10/222,506. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '506 application anticipate instant claims 1-4, 11-19, 25-38, 46-48, and 52-59. Because the same solution is subjected to the same light with a selected polarization state according to the same method steps, inherently the selected polarization state of the claimed method of the '506 application will control the resulting crystal polymorph structure to the same extent claimed in the instant application. With respect to instant claims 5, 20, 39, and 49, while the '506 application does not claim a laser wavelength of 1064 nm, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal near infrared wavelengths for the claimed method of the '506 application, because the '506 application claims the step of selecting a wavelength and because it is prima facie obvious to determine and optimize all art-recognized result-effective variables. With respect to instant claim 21, while the '506 application does not claim a power between 0.1 and 10 GW/cm², it would have been obvious to one of ordinary skill in the art to determine all operable and optimal powers for the laser light of the claimed method of the '506 application, because the '506 application claims the step of selecting a power, and because it is prima facie obvious to determine and optimize al art-recognized result-effective variables.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4, 11-19, 25-38, 46-48, and 52-59 are rejected under 35 U.S.C. 102 (f) and/or (g) as being anticipated by copending Application No. 10/222,506 and by its corresponding patent application publication, U.S. Patent Application Publication 2003/0101926. See the above provisional obviousness-type double patenting rejection.

6. Claims 5, 20, 21, 39, and 49 are rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/222,506 and by its corresponding patent application publication, U.S. Patent Application Publication 2003/0101926. See the above provisional obviousness-type double patenting rejection. This rejection assumes that copending Application No. 10/222,506 and its corresponding patent application publication, U.S. Patent Application Publication 2003/0101926, are available as prior art under 35 U.S.C. 102(f) and/or (g).

7. Claims 1, 3, 4, 6, 7, 9, 11-18, 46, 48, 50, and 52-59 are rejected under 35 U.S.C. 102(f) and/or (g) as being anticipated by U.S. Patent No. 6,596,077, which issued based upon copending Application No. 09/918,935. The claims of the '077 patent anticipate the instant

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claims. Because the same solution is subjected to the same light with the same selected polarization state according to the same method steps, inherently the selected polarization state of the claimed method of the '077 patent will control the resulting crystal polymorph structure to the same extent claimed in the instant application.

8. Claims 5 and 49 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,596,077, which issued based upon copending Application No. 09/918,935. Application of U.S. Patent No. 6,596,077 is the same as in the above rejection of claims 1, 3, 4, 6, 7, 9, 11-18, 46, 48, 50, and 52-59. While the '077 patent does not claim a laser wavelength of 1064 nm, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal near infrared wavelengths for the claimed method of the '077 patent, because the '077 patent claims the step of selecting a wavelength and because it is prima facie obvious to determine and optimize all art-recognized result-effective variables. This rejection assumes that U.S. Patent No. 6,596,077 is available as prior art under 35 U.S.C. 102(f) and/or (g).

9. The effective filing date of instant claims 1, 3, 4, 9-14, 16-18, 46, 48, 50-55, and 57-59 is deemed to be October 23, 2000, the filing date of parent application 09/694,404. These claims are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the '404 parent application because the '404 parent application, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention.

The effective filing date of instant claims 2, 5-8, 15, 19-45, 47, 49, and 56 is deemed to be September 28, 2001, the filing date of the instant application. Instant claims 2, 5-8, 15, and 19-45 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/694,404 because the '404 parent application, under the test of 35 U.S.C. 112, first

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paragraph, does not disclose the specific aging time range of 1 hour to 200 hours, does not disclose the specific wavelength of 1064 nm, does not disclose light with linear, circular, or elliptical polarization, does not disclose the specific pulse rate range of between 1 and 100 pulses per second, and does not disclose the specific power range of between 0.1 and 10 GW/cm².

10. Claims 2, 5-7, 15, 19-23, 25-42, 44, 47, 49, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Myerson (U.S. Publication No. 2003/0024470). Myerson teaches preparing supersaturated protein solutions by a combination of heating and cooling, aging the supersaturated protein solutions, and then treating the aged protein solutions with polarized laser light having a wavelength of 1064 nm and pulse rate of 10 pulses per second. The solvent can be water. Polarization can be linear or circular, the laser power can be 0.7 GW/cm², and laser treatment time can range from 0.01 to 60 seconds. Aging can last for as little as 48 hours. See e.g., paragraphs 0040, 0046, 0058, 0059, and 0064. Because the same solution is subjected to the same light with the same selected polarization state according to the same method steps, inherently the selected polarization state of the method of Myerson '470 will control the resulting crystal polymorph structure to the same extent claimed in the instant application.

11. Applicant's arguments filed September 23, 2003 have been fully considered but they are not persuasive.

The objection to Applicants' claim for priority is maintained. Applicants have not filed the necessary petition.

The provisional obviousness-type double patenting rejection over copending Application No. 10/222,506 is maintained. Although Applicants comment on how the claims of the '506 application are patentably distinct over the instant claims, the issue is only whether the instant

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claims are patentably distinct over the claims of the '506 application. Only one-way obviousness need be established to support the provisional obviousness-type double patenting rejection.

Polymorphism may be irrelevant to applications in the Protein Crystal Line; however, all crystals formed in the claimed methods of the Protein Crystal Line applications will inherently have some polymorph structure. Because the instant claims do not require that any particular crystal polymorph be achieved, and because the instant claims embrace forming "commonly nucleated" crystal polymorphs, then any polymorph structure formed in the claimed methods of the Protein Crystal Line applications will satisfy the claim requirement of the instant claims that a crystal polymorph be prepared. As set forth in the provisional obviousness-type double patenting rejection, because the same solution is subjected to the same light with the selected polarization state according to the same method steps, inherently the selected polarization state of the claimed method of the '506 application will control the resulting crystal polymorph structure to the same extent claimed in the instant application. It does not matter that the '506 application may not intend to use the polarization state to control the polymorph structure of the crystals, as long as the polarization state actually does control the polymorph structure of the crystals in the claimed method of the '506 application. Intent is not a prerequisite to inherency or anticipation. Again, Applicants have provided no explanation as to how the claimed method of the '506 application can produce a crystal of a substance and not produce a crystal polymorph.

The examiner maintains that the instant claims are anticipated by and/or obvious over the claims of copending Application No. 09/918,935, now U.S. Patent No. 6,596,077, for reasons analogous to those set forth in the above paragraph.

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As clarified by Applicants, the instant application is not commonly owned with Application Nos. 10/222,506. Accordingly, the examiner has made appropriate rejections over this application, and its corresponding Patent Application Publication, under 35 U.S.C. 102(f) and/or (g), 35 U.S.C. 102(f)/103(a), and 35 U.S.C. 102(g)/103(a) as set forth in MPEP 804, Charts I-B and III-B. The implication from Applicants' remarks concerning ownership of the applications is that the instant application and Application No. 10/222,506 also were not commonly owned at the time the invention was made, although Applicants did not explicitly address this point. Accordingly, the procedure for disqualifying these applications as prior art under 35 U.S.C. 103(c) is not available.

As clarified by Applicants, the instant application is not commonly owned with Application Nos. 09/918,935, now issued as U.S. Patent No. 6,596,077. Accordingly, the examiner has made appropriate rejections over this patent, under 35 U.S.C. 102(f) and/or (g), 35 U.S.C. 102(f)/103(a), and 35 U.S.C. 102(g)/103(a) as set forth in MPEP 804, Charts II-B. The implication from Applicants' remarks concerning ownership of the applications is that the instant application and Application No. 09/918,935 also were not commonly owned at the time the invention was made, although Applicants did not explicitly address this point. Accordingly, the procedure for disqualifying these applications as prior art under 35 U.S.C. 103(c) is not available.

The anticipation rejection based upon Myerson (U.S. Patent Application Publication 2003/0024470) is maintained. The anticipation rejection based upon Myerson '470 meets all the tests of anticipation set forth in the case law cited by Applicants. Both Myerson '470 and the instant application are directed to producing crystals from supersaturated solutions under the

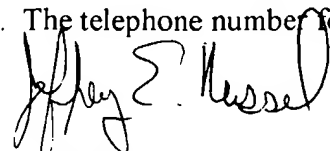
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influence of light of a selected polarization state. While Myerson '470 may have the additional benefit of creating larger and/or higher purity protein crystals, this does not mean that Myerson '470 does not produce protein crystals having a polymorph structure. Myerson '470 need not describe its invention using the exact same terminology chosen by Applicants in order to anticipate Applicants' claimed invention. See MPEP 2112 and In re Skoner, 186 USPQ 80, 82 (CCPA 1975). Myerson '470 teaches preparation of a protein crystal using an identical (not merely a similar) method as is claimed by Applicants, and Applicants' claims do not require that an "extraordinary" polymorph be produced. Accordingly, Applicants' claims do not distinguish over Myerson '470. The obviousness of the selection of a wavelength or polarization state is irrelevant in an anticipation rejection. In any event, Myerson '470 teaches selecting light of the same wavelength and the same polarization state claimed by Applicants.

12. Claims 8, 10, 24, 43, 45, and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
November 10, 2003